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Temporal trends in pregnancy outcome of Maltese Diabetic patients

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Abstract
Complications attributable to diabetes mellitus account for a significant proportion of pregnancy complications in the Maltese population. The intervention strategies that have been introduced in the last decades in obstetric practice should help to favourably alter the obstetric outcome of these pregnancies. The study reviewed the outcome indicators of pre-existing and gestational diabetic pregnancies in the Maltese population over a 15-year interval comparing the periods 1983-1986 and 1999-2002. The study has shown an increase from 0.22% to 0.35% in the prevalence of pre-existing diabetes mellitus in pregnant women, the increase being more marked in the younger age groups. The incidence of gestational DM also showed an increase from 1.25% to 2.40% reflecting a more active screening policy. In both groups, there has been a definite gain in perinatal survival and a drop in macrosomia rate; however associated with a relative rise in low birth weight resulting from earlier intervention by induction of labour and caesarian section.

Key words: *Diabetes Mellitus, Pregnancy, outcome, Malta*

Introduction

Diabetes Mellitus has become a major medical problem in the Maltese population. In the early 1980's the prevalence rate for Diabetes Mellitus in the female population of the Central Mediterranean island was found to be 15.2%. The condition was commoner in the elderly population so that the prevalence in women of reproductive age amounted to only 2.2% [Impaired Glucose Tolerance (IGT): 1.7%; Diabetes Mellitus (DM): 0.5%].[1] Diabetes in pregnancy can present itself in two clinical situations. Pregnancy can occur in a previously existing diabetic [Pre-DM], or it can appear *de novo* during pregnancy [Gestational DM]. The medical management of pregnant women suffering from diabetes in Malta has been marked by the introduction of a dedicated combined clinic. There have also been definite changes in overall obstetric practice with a greater predisposition to intervention and a rise in Caesarian section rates.[2] It is assumed that the increased metabolic surveillance and increased intervention rates would result in an improvement in obstetric outcome indicators. The present study attempts to assess the obstetric outcome changes that have occurred in the Maltese pregnant diabetic population over the last two decades.

Material & Methods

The study population was from two databases commissioned by the Department of Obstetrics-Gynaecology [Department of Health, Malta]. The first database included all the deliveries that occurred at St. Luke's Hospital, Malta during the period 1983-1986. This included a total of 20,072 deliveries with 20,335 births, accounting for about 88.7% of all the deliveries occurring on the Maltese Islands during the period. The database was collected on non-identifiable data sheets and managed by the Government Computer Center [Malta]. This database formed the basis of several annual reports and epidemiological studies including those related to diabetic pregnancies. [3] This database also contained information about diabetic pregnancies including 44 pre-DM and 251 Gestational DM and IGT [GDM/GIGT] cases as defined by the 1980 WHO criteria.[4]

The second database included all the deliveries that occurred in the Maltese Islands during the period 1999-2002. This included a total of 16,413 deliveries with 16,641 births. The data is collected and managed by the Department of Health Information [Malta] using the National Obstetric Information Service database and forms the basis of regular annual reports. This was supplemented by a specific database kept by the Diabetic Pregnancy Joint Clinic [Malta] on all diabetic pregnancies. This included a total of 16,413 deliveries of which 57 were pre-DM cases and 394 cases of GDM/GIGT as defined by the WHO criteria.

These databases furnished basic information pertaining to obstetric outcomes in the diabetic pregnancies including maternal complications, such as multiple pregnancy, induction, caesarian section, operative vaginal delivery and preterm delivery, and neonatal complications, such as perinatal mortality, low birth weight, macrosomia, low Apgar, respiratory distress and congenital malformations.

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Table 1: Diabetes in Pregnancy

Prevalence data - Pre-existing DM	1983-1986		1999-2002		P value
	No.	%	No.	%	
Pre-IDDM	[		43		
Pre-NIDDM	[44	0.22	11	0.35	p=0.027*
Pre-IGT	[		3		
Maternal Age[1]					
<35 years	33	0.19	47	0.33	P=0.504
>35 years	11	0.40	10	0.48	
Incidence data - Gestational DM/IGT					
Previous history of GDM/GIGT			25	[	
Clinically suspect GDM/GIGT			28	[	
Gestational DM	111	0.55	77	[0.79	
Gestational IGT	140	0.70	264	1.61	
Total Abnormal Glucose Tolerance	251	1.25	394	2.40	p=0.0001*
Total deliveries	20072		16413		

[*pre-IDDM: previously-existing Insulin Dependent DM; pre-NIDDM: previously-existing Non-Insulin Dependent DM; pre-IGT; previously-existing Impaired glucose tolerance*]

Table 2: Maternal and Neonatal Complications – Pre-existing DM

Complications	1983-1986		1999-2002		P value
	No.	%	No.	%	
Multiple pregnancy	0	-	2	3.5	0.503
Induction of labour	9	20.5	14	24.6	0.804
Caesarian section	25	56.8	41	71.9	0.170
Operative vaginal delivery	0	-	2	3.5	
Preterm delivery	8	18.2	12	21.1	0.985
Total deliveries	44		57		
Perinatal deaths	4	9.1	0	-	0.030*
Low Birth Weight [<2.5]	3	6.8	11	19.3	0.159
Macrosomia [>4.0 kg]	21	47.7	13	22.8	0.010*
Apgar <=6 at 5 min	3	6.8	6	10.5	0.730
Respiratory distress	0	-	12	20.0	0.005*
Congenital malformation	3	6.8	4	7.0	0.635
Total births	44		60		

Ethical considerations: No ethical restraints were associated with the study design. The study was carried out within the legal and ethical confines of the Data Protection Act [Malta], since all the data collected and processed ensured patient anonymity at all stages of the study. The relevant ethical supervisory body approved the study.

Statistical analysis: Statistical significance was tested using the Yates modification of the Chi Square test and Fisher exact tests as appropriate using the StatCalc (WHO ver.6) statistical package. A probability value of 0.05 was taken to represent a significant correlation.

Results

Pre-existing DM: The prevalence of diabetes pre-existing prior to pregnancy has varied over the last two decades. During the period 1999-2002, the prevalence rate was statistically higher than the earlier period [Table 1]. The majority [75.4%] of cases in the latter period were previously existing IDDM [pre-IDDM] cases. The age-specific prevalence rates showed that the rise noted in the 1999-2002 population was greater in the younger age group [<35 years age] than in the older group [>35 years age]. The difference was however not statistically significant [Table1]

The maternal outcome was different in the latter period though no statistical significance could be demonstrated possibly because of the small numbers involved. It appeared that the mother was subject to a slightly increased morbidity in the latter period resulting in an increased rate of intervention with induction of labour (x1.2) and caesarian section (x1.3) and preterm delivery (x1.2) [Table 2].

The obstetric outcome was more favourable in the latter period, and showed a significantly marked drop in perinatal mortality. This drop occurred in spite of a rise in preterm births (x1.2) leading to increased birth of low birth weight infants (x2.8), respiratory distress and low Apgar scores (x1.5). Only the rise in respiratory distress was however statistically significant. A statistically significant fall in macrosomia rate (x0.5) was demonstrated. There was no difference in the congenital anomaly rates [Table 2].

Gestational DM: The detection of gestational diabetes is dependent on the screening efforts during the antenatal course of the pregnancy. The incidence of abnormal glucose tolerance during pregnancy increased from 1.25% in 1983-1986 to 2.40% in 1999-2002. The difference was statistically significant. [Table 1].

Table 3: Maternal and Neonatal Complications – Gestational DM/IGT

GDM/GIGT[1]	1983-1986		1999-2002		P value
	No.	%	No.	%	
Multiple pregnancy	3	1.2	10	2.5	0.370
Induction of labour	52	20.7	188	47.7	<0.0001*
Caesarian section	41	16.3	140	35.5	<0.0001*
Operative vaginal delivery	16	6.4	17	4.3	0.330
Preterm delivery	12	4.8	41	10.4	0.019*
Total deliveries	251		394		
Perinatal deaths	5	2.0	3	0.7	0.272
Low Birth Weight [<2.5]	7	2.8	20	5.0	0.240
Macrosomia [>4.0 kg]	38	15.0	48	11.9	0.303
Apgar <=6 at 5 min	2	0.8	9	2.2	0.218
Infant with RDS	4	1.6	16	4.0	0.134
Congenital malformation	12	4.7	7	1.7	0.046*
Total births	254		403		

GDM[2]	1983-1986		1999-2002		P value
	No.	%	No.	%	
Multiple pregnancy	2	1.8	1	1.3	0.635
Induction of labour	20	18.0	35	45.5	<0.0001*
Caesarian section	24	21.6	24	31.2	0.191
Operative vaginal delivery	10	9.0	4	5.2	0.486
Preterm delivery	5	4.5	12	15.6	0.019*
Total deliveries	111		77		
Perinatal deaths	3	2.7	0	-	0.273
Low Birth Weight [<2.5]	5	4.4	9	11.7	0.110
Macrosomia [>4.0 kg]	20	17.7	10	13.0	0.502
Apgar <=6 at 5 min	2	1.8	5	6.5	0.121
Infant with RDS	3	2.7	7	9.1	0.093
Congenital malformation	6	5.3	2	2.6	0.477
Total births	113		77		

[1] based on WHO definitions of 2-hour glucose value of > 7.8 mmol/l post-75g oGTT
[2] based on WHO definitions of 2-hour glucose value of >11.0 mmol/l post-75g oGTT

The maternal morbidity in women with GDM/GIGT was significantly increased as demonstrated by greater rates of induction of labour (x2.3) and Caesarean section (x2.2). Similarly a significant increase in preterm deliveries (x2.2) was also demonstrated. The multiple pregnancy rate showed a non-statistically significant two-fold increase. The operative vaginal delivery rate showed a slight non-significant fall [Table 3]. When the maternal morbidities for severe forms [GDM] were assessed, only induction of labour and pre-term deliveries showed a statistically significant rise. The Caesarian section also showed a slightly non-statistically significant rise [Table 3].

The increased intervention rate in women with GDM/GIGT was apparently associated with a fall in perinatal mortality (x0.4) and macrosomia (x0.8). In contrast, an increase in the incidence of low birth weight (x1.8), low Apgar score (x2.8), and respiratory distress (x2.5) was recorded. These differences did not however show statistical significance [Table 3]. The incidence of congenital malformations showed a statistically significant decrease (x0.4). Similar observations were made even when more severe forms of the disorder [GDM] were considered separately [Table 3].

Conclusions

There have been differences in the profile of diabetic disorders during pregnancy in the Maltese Islands. The prevalence of pre-existing conditions has increased from 0.22% to 0.35%; the increase being more marked in the younger diabetic mother. This rising prevalence may reflect voluntary or involuntary infertility of these women in the latter period. The reported prevalence of pre-existing diabetes in the general reproductive-age female population approximated 0.5% [<35 years 0.23%; >35 years 0.92%] [1]. The 1999-2002 figure is lower than that reported in the non-pregnant population because most pregnant women are less than 40 years of age.

There was a slight, but non-significant, rise in maternal morbidity resulting from increased intervention rates through induction of labour and caesarian section. This slight rise, which may simply reflect overall obstetric practices, was attendant with a statistically significant decrease in macrosomia and perinatal mortality. There was a non-significant rise in low birth weight infants and respiratory distress. The short-term economic cost-benefit ratio of the increased intervention rate in women with pre-existing diabetes does appear to show a significant gain considering that the present analysis suggests that in order to save four children in a 100 from perinatal death, only 15 women have to undergo Caesarian section. The cost-benefit gain becomes more significant when one considers the long-term benefits for the infant through the noted two-fold decrease in macrosomia rate even though this may be offset

by the increase in low birth weight infants.[5] There was no change in the malformation rate suggesting that the concepts of pre-conceptional care have yet to be introduced in a serious and effective fashion.

The incidence of gestational diabetes and impaired glucose tolerance as defined by the WHO 1980 criteria[4] shows a definite increase from 1.25% to 2.40%. The increase may be considered reassuring. Unfortunately a previous review on gestational DM/IGT in the Maltese population had shown that a rise in incidence occurred as a result of the screening drive initiated during 1985, an intervention that helped increase the GDM/GIGT rates from 0.63% in 1983-1985 to 2.21% in 1985-86.[3] The incidence figure is very much lower than the true prevalence of gestational DM/IGT estimated in a cross-sectional study to approximate 11.5%.[6] This suggests that only about 21% of the cases are being identified using the present screening methods. It may be opportune to introduce regular screening with an oral glucose tolerance test for all pregnant women in Malta, especially in the light of the demonstrated long-term effects of even minor disorders on both the mother and child.[7,8]

Identification of GDM/GIGT cases appears to result in an increase in intervention rates that increase the morbidity to the mother and the infant. The increased intervention rate was attendant with an apparently lowered perinatal mortality and macrosomia rate; and an increase prematurity rate with its attendant problems. The minor secular changes observed in GDM/GIGT is of the same or reduced order as similar changes that have been noted to occur in obstetric practice in Malta over the last two decades. During 1999-2002, it has been shown that the management and outcome of Maltese diabetic pregnancies including both pre-existing and gestational disease was generally in line with the average outcome parameters in European centres. Marked differences were only noted in the proportion of patients with gestational diabetes who receive insulin therapy.[9]

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